



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Janell A. Colley  
Regulatory Affairs Specialist  
Sulzer Spine-Tech  
7375 Bush Lake Road  
Minneapolis, Minnesota 55439-2027

APR 20 2001

Re: P980048

BAK/Cervical (BAK/C®) Interbody Fusion System

Filed: June 22, 1999

Amended: January 28, May 25, June 22, and September 2, 1999, February 9, March 20, August 2, September 18, October 17, and November 30, 2000, January 8 and 26, February 6, 20, and 28, and April 6, 13, and 20, 2001

Dear Ms. Colley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BAK/Cervical (BAK/C®) Interbody Fusion System. This device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. BAK/C implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter. Please note that this approval requires the device to be manufactured only at the sites currently included in your PMA.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post-approval requirements in the enclosure, the post-approval reports must include the following information:

1. In order to assess the long-term safety and effectiveness of the BAK/Cervical Interbody Fusion System, please conduct a post-approval study to obtain a total of 5 years of postoperative data from a statistically meaningful number of patients based on an appropriate study hypothesis. These patients may be selected from either the IDE population, a population of post-approval implant patients or a combination of both. Please submit the protocol for your post-approval study within 30 days of receipt of this letter.
  - a. You should provide a justification which includes the following in your post-approval study protocol:
    - i. the method(s) used to select the patients and sites; and
    - ii. a description of the sample size calculations, including adjustments for lost-to-follow-up.
  - b. The data from the post-approval study should be submitted to the FDA as part of your annual report and will include the following data collected at least biennially for each patient:
    - i. a description of any surgical interventions including revisions, removals, supplemental fixations, and reoperations;
    - ii. a radiographic assessment of fusion using the same criteria employed in the original IDE study;
    - iii. an assessment of neck pain, radicular symptoms, and function using the same criteria employed in the original IDE study.
2. Because of the unknown long-term device safety and effectiveness, particularly the resulting bony fusion characteristics, the post-approval study should also contain retrieval analyses of any BAK/C device that is implanted and subsequently removed. This section of the post-approval study is not limited to the patient population described in item 1 above. Histological information (e.g., bony ingrowth quality, bone quantity, response to potential wear debris, etc.) and metallurgical information (e.g., metal wear, deformation, cracking, corrosion, etc.) should be collected and reported in the annual reports. This section of the post-approval study should continue for the duration of the study described in item 1 above.

You are reminded that it is your responsibility to maintain the plan for surgeon training in the use of the BAK/Cervical Interbody Fusion System that you submitted by electronic mail

to Ms. Hollace Saas Rhodes on April 17, 2001. Any changes to the type(s) of instructional information to be provided, including descriptions of “hands-on” sessions, should be outlined in an annual report.

Expiration dating for this device has been established and approved at 5 years based on the accelerated shelf-life testing provided. Please be advised that you are required to conduct real-time testing to validate your accelerated shelf-life testing. The results of such testing should be provided in an annual report.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at <http://www.fda.gov/cdrh/pmat/pilotpmat.html> for further details.

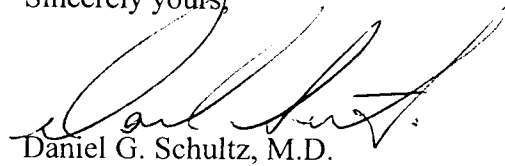
All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

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If you have any questions concerning this approval order, please contact Ms. Hollace Saas Rhodes at (301)594-2036, Ext. 165.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Daniel G. Schultz, M.D.", written over a horizontal line.

Daniel G. Schultz, M.D.  
Deputy Director for Clinical and  
Review Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure